

**2. RESPONSE**

**2.1 STATUS OF THE CLAIMS**

*Claims 1-7, 9, 12, 42-52, 61-63 and 76-83 were pending at the time of the Action.*

*Claims 6, 49, and 76-83 were cancelled herein without prejudice and without disclaimer.*

*Claims 1-5, 7, 42, and 50 were amended herein.*

*Claims 1-5, 7, 9, 12, 42-48, 50-52 and 61-63 remain pending in the case.*

*The Examiner has previously indicated allowability of claims 9, 12, and 61-63.*

**2.2 THE OBJECTION TO CLAIMS 76-83 AS REQUIRING A NEW SEARCH IS IMPROPER.**

*(The Action, Item 1)*

The Action alleges that claims 76-83 directed to fusion polypeptides that comprise the disclosed peptide sequences are improperly joinable in the present matter because they have a separate “status in the art as shown by their different classification which require non-coextensive searches.” Applicant respectfully traverses. However, given the lengthy prosecution history of the present case and the continued issuance of Actions on the merits of the case without significant progression of fundamental issues, in the interest of economics and patent term considerations, Applicant has elected to cancel these claims and to reintroduce them at a later time in an appropriate continuing application.

**2.3 THE OBJECTION TO CLAIMS 42-52 UNDER 37 CFR HAS BEEN OVERCOME.**

*(The Action, Item 2)*

The Action alleges that claim 42 is improperly multiply dependent. Applicant respectfully traverses. The present claim is an *independent claim*, and therefore, by definition, it

is not a “multiple dependent” claim. The claim merely recites in the alternative two of the elements which may be comprised within the composition. However, in the interest of economics and patent term considerations, Applicant voluntarily amends claim 42 to provide even further clarity and more particularly point out the invention to alleviate any concerns the Examiner may have had about the clarity of the previous claim.

It is clear from the present language that the claimed composition may comprise 1 of three things. Either, (a) the isolated peptide recited in claim 9, or (b) the isolated polypeptide recited in claim 7, or (c) the isolated polypeptide recited in claim 12. There is no ambiguity or confusion in the language of this independent claim, and as such, Applicant requests, therefore, that the objection be withdrawn.

#### **2.4 THE REJECTION OF CLAIMS 1-7 UNDER 35 USC 112, SECOND PARAGRAPH IS IMPROPER.**

##### ***(The Action, Items 3-5)***

The Office considers the term “about” to be indefinite. This is clearly at odds with longstanding tradition and is in conflict with specific passages of the M.P.E.P. In previous responses, Applicant has directed attention to M. P. E. P. §2173.05(b)(A) which specifically states that “the term “about” used to define the area of the lower end of a mold as between 25 to about 45% of the mold entrance was held to be clear, but flexible. *Ex parte Eastwood* 163 USPQ 316 (Bd. App. 1968).”

That section of the Guidelines further states: “Similarly, in *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), the court held that a limitation defining the stretch rate of a plastic as “exceeding about 10% per second” is definite because infringement could clearly be assessed through the use of a stopwatch.”

Only when there is evidence of close prior art (which in this case, there is none) has the court held that claims reciting “at least about” were invalid where there “was nothing in the specification, prosecution history, or the prior art to provide any indication as to what range of specific activity is covered by the term “about.” *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991).”

However, in the interest of allowance of claims to particular embodiments, and mindful of the protracted and lengthy examination process that has plagued this case, Applicant elects to amend these claims to delete the allegedly confusing term. Applicant maintains, however, that one of skill in the art would clearly understand that the phrase “about 70” is not indefinite, and that one of skill in the art would know that peptides having a length of “about 70 amino acids in length” would encompass peptides of 68 or 69 or 71 or 72 amino acids in length. Applicant also notes for the record that a peptide “of from 16 to 70 amino acids in length” would *literally* encompass those peptides of 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 60, 61, 62, 63, 64, 65, 66, 67, 68, 69 and 70 amino acids in length, and through the doctrine of equivalence, peptides of slightly larger, or slightly smaller absolute length would also meet the limitations of the present claims with respect to size.

Additionally, Applicant expressly reserves the right to pursue claims using the term “about” in a suitable continuing application. However, because the present rejection is now moot, Applicant requests that it be withdrawn and that the pending claims be allowed.

## **2.5 THE NEW MATTER REJECTION OF CLAIM 2 IS IMPROPER.**

***(The Action, Items 6 & 7)***

Claim 2 has been rejected under 35 U.S.C., section 112, first paragraph, allegedly as containing NEW MATTER. The Action at page 3, item 7 second paragraph states “claim 2 represents a departure from the specification and the claims as originally filed.” The Office asserts that “The specification and the claims as originally filed (*sic*) only support ‘An isolated peptide comprising of (*sic*) the amino acid sequence of any one of SEQ ID NOs...’” (Original emphasis). Applicant respectfully traverses.

The specification and claims as originally filed CLEARLY and UNAMBIGUOUSLY contemplates the subject matter of claim 2.

Originally-filed specification at pg 3, line 26, bridging page 4, line 4, reads:

“.....wherein the peptide comprises, consists essentially of, or consists of a first contiguous amino acid sequence according to any one of SEQ ID NO:3 through SEQ ID NO:79. Particularly preferred compositions include those peptides that comprise, consist essentially of, or consist of, the amino acid sequence of SEQ ID NO:3 or SEQ ID NO:4.” (Emphasis added)

Likewise, the original specification at page 14, lines 6 to 14 reads:

“The polypeptides of the invention also encompass those polypeptides that comprise a biologically-active p33<sup>QIK</sup> molecule, and preferably those polypeptides that consist essentially of, or consist of, an amino acid sequence of from about position 1, 2 or 3 of SEQ ID NO:2 to about position 319, 320, 321, or 322 of SEQ ID NO:2. As such, polypeptides that consist essentially of, or consist of, an amino acid sequence of from position 1 of SEQ ID NO:2 to about position 322 of SEQ ID NO:2, and those peptides that consist essentially of, or consist of, an amino acid sequence of from about amino acid residue 1 to about amino acid residue 321 of SEQ ID NO:2 are considered to fall within the scope of the invention so long as the polypeptide encodes a protein having p33<sup>QIK</sup> activity.” (Emphasis added)

Again, the original specification at page 16, lines 9 to 18 also provides LITERAL written reads:

“In another exemplary embodiment, the peptide comprises at least a first isolated peptide of from 9 to about 11 amino acids in length, or at least a first nucleic acid segment that encodes the peptide; wherein the peptide consists essentially of the amino acid sequence of any one of SEQ ID NO:3, SEQ ID NO:4, SEQ ID NO:5, SEQ ID NO:6, SEQ ID NO:7, SEQ ID NO:8, SEQ ID NO:9, SEQ ID NO:10, SEQ ID NO:11, SEQ ID NO:12, SEQ ID NO:13, SEQ ID NO:14, SEQ ID NO:15, SEQ ID NO:16, SEQ ID NO:17, SEQ ID NO:18, SEQ ID NO:19, and SEQ ID NO:20, as well as any one of SEQ ID NO:21 to SEQ ID NO:30, SEQ ID NO:31 to SEQ ID NO:40, SEQ ID NO:41 to SEQ ID NO:50, SEQ ID NO:51 to SEQ ID NO:60, SEQ ID NO:61 to SEQ ID NO:70, or SEQ ID NO:71 to SEQ ID NO:76, or from about amino acid 1 to amino acid 322 of SEQ ID NO:2.” (Emphasis added)

There is no doubt that the originally-filed specification and claims contemplated isolated (1) peptides and polypeptides that comprise one or more of the amino acid sequences set forth in the numerous identified sequences, (2) peptides and polypeptides that consist essentially of one or more of the amino acid sequences set forth in the numerous identified sequences, as well as (3) peptides and polypeptides that consist of one or more of the amino acid sequences set forth in the numerous identified sequences.

As such, claim 2, CLEARLY cannot suffer from a “new matter” rejection, because it recites the phrase “consisting essentially of” because the disputed claim language is *literally* present in *multiple* passages of the Specification as noted above. There is also no doubt that if “comprising” language and “consisting” language is clearly supported by the original Specification, that the “consisting essentially of” language in claim 2 is CLEARLY within the scope of the “open” and “closed” language.

For these reasons, Applicant requests that the rejection be withdrawn.

**2.6 THE VARIOUS REJECTIONS OF CLAIMS 1-7 AND 49 UNDER 35 U. S. C. §112, 1<sup>ST</sup> PARAGRAPH, IS MOOT.**

***(The Action, Items 8-12)***

Claims 1-7 and 49 remain variously rejected under 35 U. S. C. §112, 1<sup>st</sup> paragraph, as allegedly lacking enablement. Applicant again respectfully traverses. However, in the interest of patent term preservation, and mindful of economic concerns, Applicant has cancelled Claims 6 and 49, and amended claims 1-5 and 7, based upon the discussion between the undersigned representative and the Examiner as described below in the Interview Summary, which represent a particular sub-genus of the peptides Applicant regards as his invention. This sub-genus of peptide species encompass those sequences which literally comprise contiguous amino acid sequences contained within the full-length SEQ ID NO:2, from which peptides comprising one of the disclosed epitopes (e.g., SEQ ID NO:3, SEQ ID NO:4, or SEQ ID NO:5) are derived.

During that interview, the Office concurred that “An isolated peptide of from 16 to 70 amino acids in length, said peptide comprising a contiguous amino acid sequence from SEQ ID NO:2, that comprises the sequence of SEQ ID NO:3 (or SEQ ID NO:4, or SEQ ID NO:5) were clearly and unambiguously enabled by the Specification, and that the written description requirement for these peptide species was clearly met in the detailed teachings of the present Specification.

With respect to the issue the Examiner raised concerning the need for a biological deposit of the Krs1-NC antibody in order to ensure the ability of the skilled artisan to practice the invention for claims in which the “wherein the peptide specifically binds to a Krs1-NC antibody” limitation, Applicant appreciates Supervisory Chan’s suggestion that incorporation of the “SEQ ID NO:2 limitation in claims 1-7 obviated the need for including that limitation in the claim, and

thus obviated the need for deposit of the Krs1-NC antibody. As the Applicant is a small-entity inventor in a not-for-profit academic institution, Applicant appreciates this consideration of the Examiners during the Interview, particularly in light of the significant expense that is involved in preparing and perfecting deposit of the antibody in a Budapest Treaty depository.

As all of the Examiner's concerns have now been addressed, for these reasons, Applicant requests that each of the Section 112 rejections be withdrawn, and that all claims now proceed to allowance.

Applicant notes for the record, however, that he expressly reserves the right to re-file any and all withdrawn claims in a suitable continuing application.

## **2.7 INTERVIEW SUMMARY**

Applicant notes for the record the telephonic interview conducted by the undersigned representative 6 October 2004 with Examiners Belyavskiy, Reynolds, and Chan to discuss particular aspects of the case. Applicant appreciates the helpfulness of the Examiners in suggesting language to improve the clarity of claims 1-7, particularly highlighting those peptide species that comprise a contiguous amino acid sequence from SEQ ID NO:2 that comprises at least one of the epitopic sequences exemplified in SEQ ID NO:3, SEQ ID NO:4, or SEQ ID NO:5.

Applicant's representative also agreed to provide reference to particular passages in the Specification which demonstrated the language "consisting specifically of" was literally present in the original application, which has been done in remarks *supra*.

Finally, while Applicant's representative disagreed with the Office's position concerning the ambiguity of the word "about" in claims 1-7, agreement was reached that deletion of the phrase from those claims would obviate the Section 112, 2<sup>nd</sup> paragraph, rejection. Applicant has agreed to

this solely to advance particular claims to allowance, and reserves the right to pursue broader claims comprising the "about" language at a later date.

### 3.0 CONCLUSION

In conclusion, in light of the foregoing remarks, Applicant believes that the concerns set forth in the Action have now been overcome and that all pending claims are in condition for immediate allowance. Such favorable action is respectfully requested. Should the Examiner have any questions concerning the accompanying amendment, response and related papers, a telephone call to Applicant's undersigned representative would be greatly appreciated.

Respectfully submitted,

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Date: March 10, 2005



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